# Kansas City (KC) Inclusive Biologics and Biomanufacturing Tech Hub (KC BioHub)

**Summary**: COVID-19 demonstrated the importance of a robust public health and innovation infrastructure for vaccine development as shortages in lab supplies and an inability to find domestic producers threatened the nation's ability to develop life-saving vaccines and other preventive technologies. The global pharma market shift from small molecules to biologic drugs opens new avenues to on-shore vaccine production capacity. The Kansas City region will help lead this effort, building on our strengths in animal and human vaccine development & manufacturing and expertise in biosecurity & biodefense. Specifically, we will:

<u>Enhance Commercialization</u>: Create a new four-university platform that seamlessly scales existing commercialization programs and brings new, best-in-class programs to the region.

Create Scale-up Space: Build scale-up space in the new <u>Health Sciences Innovation District (HSID)</u> to support startups when they graduate from university incubators, providing a visible home for startups ready to access the next level of capital, equipment, expertise, management support, and workers. <u>Broaden Capital Networks</u>: Develop new capital networks that attract national investors and enhance local investors' participation in funding the region's translational animal/human health innovations. <u>Customize and Scale Training</u>: Target workforce development to the needs of vaccine producers and open doors to the inclusion of underserved workers. Create a Workforce Council where employers continually advise the region's workforce organizations on training needed; form new partnerships between employers and workforce organizations; and scale existing, successful pilot programs. <u>Deepen Collaboration</u>: Create a non-profit Contract Development and Management Organization (CDMO) to serve as a center for biomanufacturing innovation, promote inclusive workforce and entrepreneurship and be the ultimate home of the Regional Innovation Officer (RIO).

As a result, we will help to secure the U.S. vaccine supply by tripling our market share of the \$41.4B global market for human vaccine production from 4.7% to 14.2% by 2033.<sup>1</sup>

<u>Geography</u>: The KC BioHub is anchored by the Kansas City MO-KS CSA and covers a region along Interstate 70, stretching from McPherson, KS to Columbia, MO. The region includes the metropolitan areas of Manhattan, Topeka, Lawrence, KS; St. Joseph, Jefferson City, Columbia, MO; and the micropolitan areas of Atchison, McPherson, Ottawa, KS; Warrensburg, Sedalia, Marshall, MO.

<u>Geographic constraints:</u> Our region includes 28 rural counties in KS and MO.<sup>2</sup> The focus of this hub

Kansas City is the Hub of the Region's Biologics Companies

St Joseph

Kansas
City

Columbia

Waccine Companies
(# of employees)

- 25
- 150
- 151 - 500
- 101 - 400
- 401 - 1000
- 2001

Source: Author map of survey data underlying [5]

will significantly benefit underserved communities in KC. Kansas is EPSCoR- eligible.

# <u>Key Technology Focus Area (KTFA) - Biotechnology, genomics, and synthetic biology:</u> <u>Section 1: Technology-based potential of the region to achieve global competitiveness</u>

*BioNexus KC*, our Consortium Lead, was formed 25 years ago to advance the region's life science capacities at the nexus of human and animal health and has played a significant role in building the region's biotech assets. Particularly relevant is the *Animal Health Corridor*. Stretched along I-70, it boasts the largest concentration of animal health and nutrition companies in the world, including

<u>Note</u>: At first mention, the names of each Consortium member or organization offering a commitment letter are <u>underlined</u> and <u>italicized</u>.

manufacturing facilities for 4 of the top 5 global companies. These companies hold 27% of the \$11B global animal vaccine market. The region is also home to a 1,800-employee vaccine manufacturing facility in McPherson, KS, where Pfizer produces human injectable medicines, including the COVID-19 vaccine. This plant alone holds an estimated 4.7% of the \$40.2B global human vaccine market. A cluster of new human vaccine companies is developing including *Scorpius Biomanufacturing* and university spinouts *Hafion*, *Likarda*, and *Ronawk*. In total, 17 human and animal vaccine biomanufacturing firms with 5,500 employees are found in the region. As a result, the location quotient for biologic product manufacturing in the region is 2.5° and it is home to one of the nation's largest Contract Research Organization (CRO) clusters, providing the testing needed for clinical trials for pharmaceuticals nationwide, as well as the formulation and analysis that enable them to scale.

The region has also built world-class assets in biosecurity and biodefense. The <u>National Bio- and Agro-defense Facility (NBAF)</u> is the first line of biodefense against zoonotic disease and one of only seven Biosecurity Level 4 (BSL-4) facilities in the U.S.<sup>7</sup> It is supported by <u>Kansas State University (KSU)</u>'s Biosecurity Research Institute, which received a 2023 \$1M NSF Engine Type 1 award focused on biosecurity, biodefense, and biomanufacturing. <u>MRIGlobal</u> develops and tests vaccines and therapeutics to safeguard public, occupational, and military health, and the <u>University of Missouri – Kansas City</u> (<u>UMKC</u>) Midwest Institute for Defense & Energy unites researchers and the community in the development and prototyping of new technologies for national security and dual-use markets.

Area research institutions play significant roles in vaccine development. Collectively they have received \$122M of HHS and NIH funding over the past five years for vaccine research. At the *University of Missouri (MU)*, the interdisciplinary Roy Blunt Precision Health Institute and the 10-megawatt Research Reactor (the most powerful University research reactor in the U.S.) support discovery. At the *University of Kansas (KU)*, the Vaccine Analytics and Formulation Center has developed new mRNA vaccines, and \$12 million in interdisciplinary projects are revolutionizing the use of big data for drug discovery and growing faculty strength in genomics.

The Kansas City regional startup ecosystem is strong, providing comprehensive support and early-stage capital access for small businesses and tech startups. Assets such as the <u>Kauffman Foundation</u> and <u>UMKC</u> Innovation Center's (UMKC IC) national SourceLink program not only provide local support but drive efforts across the country to improve inclusion in entrepreneurial ecosystems.

By building on these assets and taking advantage of technological advances like mRNA vaccines that allow greater potential for on-shoring, we believe the KC region will capture an outsized share of the 10% annual growth of the \$40.4B human vaccine market, with our region tripling its share from 4.7% to 14.2% over the next decade as the global market increases to over \$100B.<sup>1</sup>

#### Section 2: Role of the private sector

<u>CEVA</u>, <u>Scorpius</u>, <u>TriRX</u>, <u>Eurofins Viracor</u>, <u>5 CROs and CDMO</u>s representing a larger cluster, and <u>seven startups</u> are Consortium industry members and have committed to making facility and hiring investments in our region, led by Scorpius' \$650M new biomanufacturing plant construction. All industry partners have committed to mentoring startups and participating in our Workforce Council to identify areas where workforce investment is needed and either attract or create programs to fill those talent gaps. The group will also recommend pathways for post-secondary education (esp. community colleges) to align academic programs and industry needs.

The region, led by UMKC IC and *KC Rising* (the region's business-led civic collaborative whose mission is to "Grow the Economy For Everyone"), has been working to increase venture investment in regional startups and, since 2015, the region has more than doubled the grant, debt, and equity capital available to early-stage companies. Every university in the region offers pre-seed funding opportunities for companies spinning out of their own research, and further prototyping funding is available through the UMKC Digital Sandbox program, created with EDA RIS funding in 2014. The BioNexus KC Nexus Fund, which was formed with funding from the EDA's Build-to-Scale program, will reach its first close in 2023 and will be a \$10M seed-stage fund ready to invest in regional biologics and biomanufacturing startups. *AltCap*, a regional CDFI, has significantly increased resources and has committed to expanding its ability to finance startup manufacturing, components, and logistics firms.

# Section 3: Regional Coordination and Partnerships

In 2020, KC\_Rising commissioned research by the Brookings Institution that recommended biologics as the next cluster to prioritize for regional investment. A task force forming the core of the consortium worked for three years to understand the cluster's needs and opportunities, yielding analyses

such as a life sciences census, <sup>10</sup> a regional R&D assessment, <sup>11</sup> a biologics industry workforce and skills report, <sup>12</sup> and a series of focus groups recommending DEI improvements in the industry. In turn, this work spurred the region's acceptance into the 2-year <u>MIT Regional Entrepreneurship Acceleration</u>

<u>Program</u> (MIT REAP) – making KC only the third U.S. region to participate – to dig deep into biologics & biomanufacturing startup needs. Over time, the Consortium core expanded to include all of the organizations diagrammed at right. Lead BioNexus KC plans to initially hire the RIO who will continually engage members to set targets and hold themselves

Research
Government
Industry
Workforce
Eco Devo

4 Public
Universities
Congress
3 Corporations
7 Scholacal Colleges
28 Bural Counties
Scrivie Firms
3 Other Research
Nettrutions

6 Metres
7 Startups
1 Counties
1 Council of
Olivernments
1 Scholacalitions
1 Scholararitip
Provider

accountable for achieving them. The RIO will also work with state and local economic development officials to develop programs and incentives better targeted to encourage biomanufacturing.

#### Section 4: Equity, Diversity, and Inclusion

The Consortium's focus on biomanufacturing means generating access to thousands of new, living-wage jobs for historically underrepresented populations without a college degree. We will improve their chances of benefiting from these jobs by meaningfully engaging the community in master planning the HSID in the recently established *KCMO* Community Improvement District (CID). Led by UMKC, the HSID is located adjacent to the region's largest concentration of underrepresented population, and will: a) develop a biomanufacturing training center for upskilling and credentialing area residents, potentially repurposing the historic Wheatley-Provident Hospital building, which was the first entirely Black staffed, administered, and serving hospital in the United States; b) develop career pathways, internship and apprenticeship programs targeted at underrepresented youth; b) spur equitable wealth creation by emphasizing entrepreneurial opportunities for underrepresented people; and c) improve the economic and physical health of the region's urban core as KCMO has taken steps to establish an associated Benefits District to redirect tax revenue to neighborhood affordable housing.

This work will be supported by current Consortium members that represent historically underserved

communities including <u>Donnelly College</u>, an Hispanic- and Minority-serving Institution (HSI/MSI), KC Rising, the <u>PREP KC/KC STEM Alliance/KC Scholars</u> trio of organizations supporting underserved students, CDFI AltCap, and the UMKC IC's KCSourcelink network, many of whose 230+ partner Entrepreneurship Support Organizations (ESOs) are wholly dedicated to serving entrepreneurs of color. UMKC IC serves more than 4,000 entrepreneurial businesses each year, 38% of which identify as BIPOC, far surpassing their 9.5% share of the region's business owners and their 30% share of the region's population. <sup>14</sup> Focusing this entrepreneurial ecosystem on biomanufacturing and its supply chain will aid wealth creation by increasing minority-owned businesses' growth.

# Section 5: Composition and capacity of the regional workforce

To reach globally competitive hub status by 2033, the region aims to triple the number of jobs in biomanufacturing, which requires expanding the talent pipeline and unlocking the potential of <u>all</u> residents. Analysis shows the existing talent base and workforce initiatives provide a strong foundation for sector growth and diverse worker access to quality jobs.

Brookings' research on "talent adjacencies" between occupational demands in biologics and the region's prevalent traded sectors revealed a 90% overlap in core technical knowledge and skills, with moderate gaps able to be filled by specialized training. Moreover, Brookings found the sector disproportionately concentrates opportunities for workers to get ahead, where 50% of jobs offer upward mobility, and nearly 30% are in middle-skill occupations not requiring a four-year degree. <sup>15</sup>

The region's nationally-recognized workforce initiatives in STEM and biologics are ripe for accelerated scale-up, with sector-specific connections with mainstream programs to extend the talent pipeline. The White House-lauded NIST NIIMBL experience pilot run by *BioKansas* is a biopharmaceutical manufacturing immersion program targeted at Black, Latino, and Indigenous community college and university students. The *Bioscience Core Skills Institute* provides entry-level credentialing. *MATC* offers an HVAC technician training program to support secure BSL-2 and BSL-3 lab facilities. A new biomanufacturing training program among the *Full Employment Council (FEC)*, TriRX, CEVA, Ronawk, BioNexus, *Metropolitan Community College*, and others gives students wraparound services; BioBuilder & BioMade programs will be pursued to enhance student experiences.

More broadly, the Consortium's *three community and technical colleges*, Donnelly College, and workforce boards from both states: the KS *Workforce Partnership* and the MO FEC are committed to prioritizing sector needs within their adult education, job training, and re-training, and certificate programs, as well as apprenticeships. Similarly, the KC STEM Alliance, PrepKC, the *CAPS Network*, and the 30-district Real World Learning program led by the Kauffman Foundation deliver models for engaging diverse K-12 students in programs where they graduate with work experience and have identified biologics and biomanufacturing as relevant fields to integrate for STEM career exposure.<sup>16</sup>

## Section 6: Innovative lab-to-market approaches

The region's combination of corporate and public R&D across biologics products and production is a distinctive strength. Brookings found 25% of the region's published research is conducted with business, predominantly in life sciences, nearly twice the U.S. metro average, evincing an orientation to application. Strategies that expand this base of joint problem-solving with industry can capture the place-based benefits of translation, commercialization, and manufacturing through three phases: **Lab-to-Pilot**: The research volume of the Consortium's four research universities can rival the

commercialization of coastal institutions<sup>18</sup> if they collaborate to achieve the critical mass of accessible innovation capacity. The institutions commit to building a shared platform to improve tech transfer agreements and policies, plus exploring promotion and tenure guidelines that encourage business engagement and entrepreneurship, capital campaigns for endowed professorships in applied research, and Global EIR programs to retain foreign-born talent post-graduation. They also will jointly establish an NSF i-Corps node in the region to attract best-in-class commercialization programs like Creative Destruction Lab and MIT Engine's Whiteboard. Finally, they will extend partnerships with Tribal University Haskell Indian Nations U. and HBCU Lincoln U.

**Pilot-to-Trial**: While the research universities and other regional supports have incubator facilities for spinning out biologics startups, these often leave the region to scale. Through MIT REAP the group developed three priorities to address this gap: 1) BSL-2 lab space to aggregate the spinouts from area universities and efficiently support the needs of growing bioscience startups; 2) increased access to capital from inside and outside the region; 3) programs to help entrepreneurs navigate the regulatory environment faced by biologics innovators. Space needs will be addressed by a scale-up lab inside the HSID, enabling entrepreneurs to draw on adjacent expertise at UMKC's medical schools, Children's Mercy Hospital's rare disease treatment research programs, and University Health's safety net hospital. Capital needs will be addressed by sector targeting of new and regionally-focused KC Rise venture fund, events drawing national interest like the BioKansas Innovation Festival and Mid-by-Midwest, and proactive outreach facilitated through the RIO for scale and visibility.

**Trial-to-Market:** To capture large-scale job creation and production, a novel, community-engaged non-profit CDMO in the HSID will serve as a center for biomanufacturing innovation and promote inclusive workforce development and entrepreneurship; it also be the ultimate home of the RIO and sector cluster leadership. Through this mechanism, efficiency in bringing startup biologics production from trial to market will be accelerated by tapping the ability of KU and Children's Mercy to conduct large clinical trials (supported by a \$27M NIH Frontiers in Health grant) and CRO cluster expertise in regulatory processes. The CDMO will ensure the drugs developed are validated with diverse clinical trials and designed to benefit historically marginalized populations. With the addition of these new supports, the region has every capability needed to bring a biologic drug to the public, from peptide production, batch formulation, and analytics to a repository, a biorepository, a foreign trade zone, and proximity to cold storage logistics infrastructure with intermodal capacity.

## Section 7: Impact on the economic and national security of the United States

COVID-19 demonstrated the importance of rapid development and deployment of vaccines as national security and the need for increased domestic production. Since 75% of all new infectious diseases are zoonotic in origin, NBAF and strengths in biosecurity and biodefense, as well as vaccine manufacturing capacity, make the region critical to protecting human health. Designation as a tech hub will catalyze our transition from leadership in animal vaccines to human vaccines, scaling domestic production and protecting our country against the threat of future pandemics. Due to the strong concentration of biodefense assets, the region could stand up a centralized secure vaccine scaling facility that would complement the countermeasures mission of BARDA, the NIAID, and the National Defense Strategy. As a result, KC's BioHub will expand domestic biomanufacturing infrastructure, increase our national resilience, and position this region as a leader in a growing global market.

# **Appendix: Notes and Citations**

- 1. Author's calculations, based on market data reports and privately collected data, available for review at <a href="http://bit.ly/KCBioHubMarket">http://bit.ly/KCBioHubMarket</a>.
- 2. Doniphan, Atchison, Leavenworth, Miami, Linn, Douglas, Shawnee, Wabaunsee, Riley, Geary, Dickinson, Saline, and McPherson, Counties in KS; Platte, Clay, Ray, Cass, Bates, Clinton, Caldwell, Lafayette, Buchanan, Johnson, Pettis, Saline, Cooper, Boone, and Cole Counties in MO.
  - 3. "About the Corridor." *About, ThinkKC,* <u>kcanimalhealth.thinkkc.com/about</u>.
- 4. "PGS McPherson, Kansas." Pfizer, <u>www.pfizer.com/products/pfizer-global-supply/us-manufacturing-sites/mcpherson</u>.
- 5. "Kansas City Regional Biologics R&D Landscape", Latham BioPharm Group, June 2022. <a href="www.bionexuskc.org/reportsforedatechhubs/">www.bionexuskc.org/reportsforedatechhubs/</a>. This report was published prior to Scorpius' relocation to the region and does not include the Pfizer plant and its' 1,800 employees. With the addition of those two facilities, the region holds 17 biomanufacturing firms and 5,500 jobs.
  - 6. Report from Lightcast, 2023.
- 7. "Mapped: Maximum containment labs around the world." *Bulletin of the Atomic Scientists*, <a href="https://thebulletin.org/global-biolabs/#post-heading">https://thebulletin.org/global-biolabs/#post-heading</a>. NBAF is one of just seven active BSL-4 labs in the US and one of just 55 such facilities worldwide.
- 8. Author's calculations, based on a 2022 search of HHS and NIH funding records via <a href="https://reporter.nih.gov/">https://reporter.nih.gov/</a> covering years 2018-2022.
  - 9. "Metro Kansas City's Traded Cluster Assets." *Brookings Institution*, <u>kcrising.com/resources/metro-kansas-citys-traded-cluster-assets/</u>.
- 10. "Kansas City Regional Life Sciences Census 2021." *BioNexus KC*, www.bionexuskc.org/reportsforedatechhubs/.
  - 11. "Kansas City Regional Biologics R&D Landscape", Latham
- 12. "Biologics TIE Insights KC Rising." *Clear Box Insights*, www.bionexuskc.org/reportsforedatechhubs/.
  - 13. "Historic Wheatley Provident Hospital." <a href="https://www.wheatleyprovident.com/">https://www.wheatleyprovident.com/</a>.
- 14. Author's calculations, based on data from the 2018 American Business Survey and 2021 American Community Survey, 1-year data, U.S. Census Bureau.
- 15. According to Brookings, a good job pays at least \$23.70/hr or \$47,000/yr, based on living wage data from the University of Washington, and has health insurance (in line w/ DOC and DOL Good Jobs standards), while a promising job will achieve this level in 10 years.
  - 16. "Real World Learning." Kauffman Foundation, https://realworldlearning.org/.
- 17. "Building the Bioworkforce of the Future." White House Office of Science and Technology Policy, <a href="https://www.whitehouse.gov/wp-content/uploads/2023/06/Building-the-Bioworkforce-of-the-Future.pdf">https://www.whitehouse.gov/wp-content/uploads/2023/06/Building-the-Bioworkforce-of-the-Future.pdf</a>.
- 18. Author's calculations, based on data from the NSF NCSES on R&D Expenditures. When added, the expenditures of MU. KU, KSU, and UMKC ranked #25 among U.S. universities in 2021.
- 19. Salyer, Stephanie J., et al. "Prioritizing Zoonoses for Global Health Capacity Building—Themes from One Health Zoonotic Disease Workshops in 7 Countries, 2014–2016." *Emerging Infectious Diseases*, vol. 23, no. 13, 2017, https://doi.org/10.3201/eid2313.170418.